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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,915	09/09/2003	Kenneth M. Adams	M190.145.101	7670

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/657,915	Applicant(s) ADAMS ET AL.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/21/2005,09/09/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-24, in the reply filed on 11/10/2006 is acknowledged.

Claims 25-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/10/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-10, 13-17 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams (U.S. Patent No. 6,503,263).

Adams discloses a surgical micro-burring instrument see FIG. 2 and FIG. 4A-B) comprising an outer tubular member (ref. #18) having a proximal section, an intermediate section, a distal section, and a central lumen (ref. #36) extending from the proximal section to the distal section, the distal section forming a pocket (ref. #65) fluidly connected to the central lumen, the pocket having a bottom surface and an opposed upper opening; an elevator tip extending distal the pocket; and an inner tubular (ref.

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#22) member rotatably received within the central lumen, a distal end of the inner tubular member forming a bur (ref. #150) positioned within the pocket. Upon final assembly, at least a portion of the bur is exposed relative to the outer tubular member via the upper opening of the pocket (functional/intended use recitation). The pocket terminates at a distal-most end. The elevator tip includes an upper surface extending from the distal-most end of the pocket, the upper surface including a proximal region and a distal region, wherein at least a portion of the distal region extends from the proximal region in an angular fashion in longitudinal cross-section. At least a portion of the proximal region of the top surface of the elevator tip extends downwardly from the distal-most end of the pocket. The proximal region is curved in longitudinal cross-section. The elevator tip terminates in a distal end point, and further wherein the distal end point is laterally above the distal-most end of the pocket when the outer tubular member is oriented such that the bottom surface of the pocket is below the upper opening. The distal section further includes a proximal portion proximal the pocket, the proximal portion forming a tube, and further wherein the pocket is defined by a sidewall having an upper edge including a proximal zone extending from the proximal portion in an angularly downward fashion. The upper edge further includes an intermediate zone extending from the proximal zone parallel with a central axis of the proximal portion. The upper edge further includes an intermediate zone extending from the proximal zone, and a distal zone extending from the intermediate zone, the distal zone extending downwardly relative to the intermediate zone. The lower surface forms at least one opening (ref. #38) fluidly connected to an irrigation source. The instrument further

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comprises an irrigation tube (ref. #24) extending exteriorly along the outer tubular member and fluidly connected to the at least one opening. The pocket is further terminates at a distal-most end point, and further wherein upon final assembly, a distal end of the bur is longitudinally spaced from the distal-most end point. The instrument is adapted for use in a septoplasty procedure (functional/intended use recitation). The elevator tip is selectively axially moveable relative to the bur.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-8 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263).

Adams discloses the claimed invention except for the following ranges and optimum values: the elevator tip distally extending at least 0.05 inch relative to the distal-most end of the pocket, the angular extension of the distal region defining an included angle in the range of 10 degrees-50 degrees relative to a central axis of the outer tubular member, specifically 20 degrees and 40 degrees, the angular extension of the proximal zone defining an included angle in the range of 100 degrees-140 degrees relative to a central axis of the proximal portion, specifically approximately 120 degrees. It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to construct the device of Adams with the elevator tip distally extending at least 0.05 inch relative to the distal-most end of the pocket, the angular extension of the distal region defining an included angle in the range of 10 degrees-50 degrees relative to a central axis of the outer tubular member, specifically 20 degrees and 40 degrees, the angular extension of the proximal zone defining an included angle in the range of 100 degrees-140 degrees relative to a central axis of the proximal portion, specifically approximately 120 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art and it has also been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) in view of Adams (U.S. Patent No. 6,312,438).

Adams '263 discloses the claimed invention except for an aspiration passage extending through the outer tubular member for aspirating cut tissue and the inner tubular member forms a lumen defining the aspiration passage with the bur forming an opening at a distal end thereof, and further wherein the opening is in fluid communication with the lumen of the inner tubular member.

Adams '438 discloses an aspiration passage extending through the outer tubular member for aspirating cut tissue and the inner tubular member forms a lumen defining the aspiration passage with the bur forming an opening at a distal end thereof, and

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further wherein the opening is in fluid communication with the lumen of the inner tubular member (col. 3, lines 36-46) in order to define a suction passage through the inner member by which debris, such as tissue, blood, and saline, is aspirated.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams '263 with an aspiration passage extending through the outer tubular member for aspirating cut tissue and the inner tubular member forms a lumen defining the aspiration passage with the bur forming an opening at a distal end thereof, and further wherein the opening is in fluid communication with the lumen of the inner tubular member in view of Adams '438 in order to define a suction passage through the inner member by which debris, such as tissue, blood, and saline, is aspirated.

Claims 20-21 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) in view of Adams (U.S. Patent No. 6,312,438).

Adams '263 discloses the claimed invention except for the intermediate section of the outer tubular member defining a longitudinal bend approximately 12 degrees relative to a central axis defined by the proximal section.

Adams '438 discloses the intermediate section of the outer tubular member defining a longitudinal bend approximately 12 degrees relative to a central axis defined by the proximal section (col. 4, lines 65-67) in order to provide access to surgical sites (col. 1, lines 45-50)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams '263 with the intermediate section

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of the outer tubular member defining a longitudinal bend approximately 12 degrees relative to a central axis defined by the proximal section in view of Adams '438 in order to provide access to surgical sites.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (U.S. Patent No. 6,503,263) in view of West, Jr. (U.S. Patent No. 5,364,395).

Adams discloses the claimed invention except for an intermediate tubular member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member.

West, Jr. discloses an intermediate tubular (ref. #92) member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member in order to provide an electrically insulative layer (col. 9, lines 55-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Adams with an intermediate tubular member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member in view of West, Jr. in order to provide an electrically insulative layer.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER